

improve glycemic control in adults with type 2 diabetes mellitus. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ONGLYZA (U.S. Patent No. 6,395,767) from Bristol-Myers Squibb Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 3, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ONGLYZA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ONGLYZA is 2,794 days. Of this time, 2,397 days occurred during the testing phase of the regulatory review period, while 397 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* December 8, 2001. The applicant claims November 8, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 8, 2001, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* June 30, 2008. FDA has verified the applicant's claim that the new drug application (NDA) for ONGLYZA (NDA 22-350) was submitted on June 30, 2008.

3. *The date the application was approved:* July 31, 2009. FDA has verified the applicant's claim that NDA 22-350 was approved on July 31, 2009.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 896 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments and ask for a redetermination by November 1, 2010. Furthermore, any interested

person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by [insert date 180 days after date of publication in the **Federal Register**]. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document. Comments and petitions that have not been made publicly available on regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 13, 2010.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. 2010-21583 Filed 8-30-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-D-0431]

#### **Draft Guidance for Food and Drug Administration Staff and Tobacco Retailers on Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers." This guidance document is intended to describe FDA's current policies with respect to civil money penalties and no-tobacco-sale orders for retailers who violate requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) relating to tobacco products, including the FD&C Act requirement that tobacco products may not be sold or distributed in violation of FDA's

"Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." When this guidance document is final, several provisions in the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) that relate to civil money penalties and no-tobacco-sale orders will become effective.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 1, 2010.

**ADDRESSES:** Submit written requests for single copies of the guidance entitled "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers" to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### **FOR FURTHER INFORMATION CONTACT:**

Gerie A. Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373, [gerie.voss@fda.hhs.gov](mailto:gerie.voss@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for FDA Staff and tobacco retailers entitled "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers." On June 22, 2009, President Obama signed the Tobacco Control Act (Public Law 111-31) into law. The Tobacco Control Act grants FDA important new authority to regulate the manufacture, marketing and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Among its many provisions, the Tobacco Control Act authorizes FDA to impose civil money penalties for violations of FD&C Act requirements that relate to tobacco products (section 303(f)(9) of the FD&C Act (21 U.S.C. 333

(f)(9)). Of special interest to retailers, one of the FD&C Act's requirements is that tobacco products may not be sold or distributed in a manner that violates regulations issued under section 906(d) of the FD&C Act, such as the "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" that were published by FDA in the **Federal Register** of March 19, 2010 (75 FR 13225) (21 CFR part 1140). The Tobacco Control Act also authorizes FDA to impose a no-tobacco-sale order on a retail outlet for repeated violations of regulations issued under section 906(d) of the FD&C Act, and discusses a number of technical and procedural issues relating to civil money penalties and no-tobacco-sale orders.

The draft guidance document describes the penalty structure and draft FDA policies with respect to civil money penalties and no-tobacco-sale orders. When this guidance is final, several Tobacco Control Act provisions that relate to civil money penalties and no-tobacco-sale orders will become effective (section 103(q)(3) of the Tobacco Control Act).

## II. Significance of Guidance

FDA is issuing this draft guidance document as a level 1 draft guidance consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). The draft guidance, when finalized, will represent the agency's current thinking on "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Comments

Interested persons may submit to the Division of Dockets Management (See **ADDRESSES**), electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/TobaccoProducts/GuidanceCompliance>

*RegulatoryInformation/default.htm* or <http://www.regulations.gov>.

Dated: August 26, 2010.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflict: Alcohol.

*Date:* September 29, 2010.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call.)

*Contact Person:* Michael Selmanoff, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3134, MSC 7844, Bethesda, MD 20892. 301-435-1119. [mselmanoff@csr.nih.gov](mailto:mselmanoff@csr.nih.gov).

*Name of Committee:* Oncology 1—Basic Translational Integrated Review Group, Tumor Microenvironment Study Section.

*Date:* October 4-5, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Ritz-Carlton, Washington, DC, 1150 22nd Street, NW., Washington, DC, 20037.

*Contact Person:* Eun Ah Cho, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6202, MSC 7804, Bethesda, MD 20892. (301) 451-4467. [choe@csr.nih.gov](mailto:choe@csr.nih.gov).

*Name of Committee:* Biological Chemistry and Macromolecular Biophysics Integrated Review Group, Synthetic and Biological Chemistry A Study Section.

*Date:* October 7-8, 2010.

*Time:* 8 a.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Mike Radtke, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7806, Bethesda, MD 20892. 301-435-1728. [rادتke@csr.nih.gov](mailto:rادتke@csr.nih.gov).

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review Group, Neural Basis of Psychopathology, Addictions and Sleep Disorders Study Section.

*Date:* October 7-8, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites Washington, DC, 1250 22nd Street, NW., Washington, DC 20037.

*Contact Person:* Boris P Sokolov, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892. 301-408-9115. [bsokolov@csr.nih.gov](mailto:bsokolov@csr.nih.gov).

*Name of Committee:* Oncology 1—Basic Translational Integrated Review Group, Cancer Etiology Study Section.

*Date:* October 7-8, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Marina del Rey Marriott, 4100 Admiralty Way, Marina del Rey, CA 90292.

*Contact Person:* Elaine Sierra-Rivera, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892. 301-435-1779. [riverase@csr.nih.gov](mailto:riverase@csr.nih.gov).

*Name of Committee:* Oncology 1—Basic Translational Integrated Review Group, Cancer Genetics Study Section.

*Date:* October 7-8, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Doubletree Hotel Washington, DC, 1515 Rhode Island Avenue, NW., Washington, DC 20005.

*Contact Person:* Steven F. Nothwehr, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5183, MSC 7840, Bethesda, MD 20892. 301.408.9435. [nothwehrs@mail.nih.gov](mailto:nothwehrs@mail.nih.gov).

*Name of Committee:* Digestive, Kidney and Urological Systems Integrated Review Group, Pathobiology of Kidney Disease Study Section.

*Date:* October 7, 2010.

*Time:* 8 a.m. to 7 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Atul Sahai, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge